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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,580	09/23/2005	Martin F. Bachmann	1700.0610001/BJD/WBC	8355

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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KINSEY WHITE, NICOLE

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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01/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/550,580	Applicant(s) BACHMANN ET AL.	
	Examiner Nicole Kinsey White, PhD	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 is/are rejected.
- 7) ☒ Claim(s) 12, 14, 15, 17-19 and 115-118 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-12,14,15,17-19,21,24,25,27,30,33,35,42,48,49,94-99,102-104 and 108-112.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,6,7,9-11,49,94-96,98,99,102-104,108-110,112,113 and 114.

### **DETAILED ACTION**

In the reply filed on October 11, 2007, applicants state that claims 8 and 10 read on the elected species and should be rejoined and examined. Claim 8 has been under examination. Claim 10 does not read on the elected sequences (SEQ ID NOs:72 and 85). SEQ ID NOs:75 and 76 from claim 10 are different from SEQ ID NOs:72 and 85.

### ***Withdrawn Rejections***

The rejection of claims 8, 42 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1, 2, 8, 12, 14, 15, 17, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. has been withdrawn in view of applicants' Declaration under 37 C.F.R. § 1.132.

The rejection of claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. has been withdrawn in view of applicants' Declaration under 37 C.F.R. § 1.132.

***Maintained Rejections***

***Double Patenting***

Claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42 and 48 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 14-16, 41, 48 and 55 of copending application 10/563,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant composition claims are obvious over the claims of the copending application because the claims of the copending application have all of the characteristics of the instant composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***New Rejections***

***Claim Rejections - 35 USC § 112***

Claims 97 and 111 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

*Nature of the invention.* The instant invention is drawn to a vaccine for HIV. The term "vaccine," by definition, implies a preparation intended for active immunological

prophylaxis. Prophylaxis is defined as the prevention of disease or of a process that can lead to disease.

*State of the prior art.* It is well known in the art and even to the general public that medical science, despite decades of intense research, has not found any antigen, immunogen, or compound that can be credibly used as a vaccine against HIV.

The difficulties inherent to developing an HIV vaccine are well known. For the sake, of clarity, some of those problems are outlined here:

1) the extensive genomic diversity associated with HIV, due in large part to error prone reverse transcription of its RNA genome,

2) the fact that the modes of viral transmission include virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert form (cell to cell transmission), as well as via free virus transmission,

3) the existence of latent forms of the virus,

4) the complexity and variation of the elaboration of the disease, and

5) the property of some portions of HIV proteins or peptides to actually cause immunosuppression or other detrimental consequences.

The existence of these obstacles prevents one of ordinary skill in the art from accepting any therapeutic regimen on its face given the intense interest in developing HIV treatments or vaccines and the lack of success in doing so.

*Working examples.* The specification contains examples showing the immunogenicity of the VLPs. None of the examples, however, show complete protection where there is prevention of HIV infection. There are no examples showing

vaccination with a VLP and challenge with HIV resulting in complete protection or prevention of HIV infection.

*Guidance in the specification.* The claimed invention is directed to a vaccine against HIV. There is insufficient disclosure to reasonably predict that the claimed vaccine of the instant specification would prevent HIV infection. In addition, the disclosure fails to provide any guidance pertaining to the correlates of human protection. To date, it is not clear what type of immune response is required to provide a therapeutic benefit.

The disclosure also fails to provide any guidance pertaining to the development of a persistent and protective HIV-1-specific immune response. It is not readily apparent if the recited HIV vaccine will generate an HIV-1-specific immune response of sufficient magnitude and duration that long-lasting protection against HIV-1 infection and the development of AIDS would be provided.

While the specification does contain statements regarding the use of the VLPs as an HIV vaccine, there is no indication that an HIV-1-specific immune response has been generated and that such a response, if generated, would be protective following exposure to HIV-1. Applicants have not provided any evidence in the instant specification that the disclosed VLPs can prevent HIV infection or HIV-1 transmission following the administration of said vaccine.

*Predictability or unpredictability of the art.* The state-of-the-art vis-a-vis HIV vaccine development is one of unpredictability (Haynes et al., 1996; Burton and Moore, 1998; Moore and Burton, 1999; Desrosiers, R., 2004). To date, there is not one single

effective HIV vaccine on the market. Several clinical trials have been conducted but in every situation, the immunogen failed to induce a long-lasting and high-titer immune response.

Accordingly, when all the aforementioned factors are considered *in toto*, it would require undue experimentation for one skilled in the art to practice the claimed invention.

The elected species SEQ ID NOs: 71, 72 and 85 are allowable. Claims 12,14,15,17-19 and 115-118 are objected to as being dependent upon a rejected base claim, but would be allowable, as they read on the elected species, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole Kinsey White, PhD whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole Kinsey White, PhD  
Examiner  
Art Unit 1648

/nkw/

/Stacy B. Chen/ 1-7-2008  
Primary Examiner, TC1600